

September 17, 2021

## HHS Reinstates Original Distribution Method for COVID-19 Monoclonal Antibody Therapies

*ASPR is working with state and territorial leaders to make COVID-19 monoclonal antibody therapies available across all states and territories. The therapies no longer can be ordered directly by hospitals.*

The Department of Health and Human Services' (HHS) Assistant Secretary for Preparedness and Response (ASPR) Sept. 13 [announced a major change](#) in the distribution of COVID-19 monoclonal antibody therapies. This change was prompted by the rapid surge in COVID-19-positive cases across the country, which has greatly increased the demand for monoclonal antibodies as a therapy that has been shown to be effective for many people in preventing severe illness or death if administered early in the course of the disease.

The first monoclonal antibody therapies received Food and Drug Administration emergency use authorization in November 2020, with supplies having since been limited. The initial demand for monoclonal antibodies was much lower than available supply, which is why from February 2021 until Sept. 13, ASPR allowed hospitals and other health care delivery sites to order monoclonal antibodies directly from the supplier (AmerisourceBergen). However, the rapid increase in demand for monoclonal antibodies has significantly constrained supply. To assure an equitable distribution of what has now become a limited resource, the federal government has reverted to the method it used from November 2020 through February 2021 for allocating monoclonal antibodies. It is similar to the method HHS used to allocate COVID-19 vaccines at a time when they, too, were in limited supply.

### Key Takeaways

- As of Sept. 13, hospitals and other facilities administering monoclonal antibody therapies to COVID-19-positive patients must work through their state or territorial government to obtain those medications.
- ASPR will allocate monoclonal antibody supply to each state and territory on a weekly basis using the data reported to HHS Protect on the number of COVID-19 cases and hospitalizations as well as the use rate for previously received monoclonal antibodies.
- Governors or their designees will be empowered to accept all or some portion of that allotment and instruct AmerisourceBergen how to distribute its accepted allotment within the state.
- Any unallocated portion of the shipment will be retained to use in responding to unforeseen needs during the week or added to the next week's shipment.

## THE ALLOCATION METHOD

ASPR begins each week by learning from the manufacturers how many doses of monoclonal antibodies will be available. It then uses data collected from hospitals and other providers that is sent to HHS Protect to determine each states' COVID-19-positive case counts and number of hospitalized patients. These numbers determine the proportion of available monoclonal antibodies each state might receive, but it will be adjusted if a state's usage rate for monoclonal antibodies suggests it is not using up its prior week's allocation at a rate similar to that of other states.

Each state governor or their designee will receive notice of the amount to be sent to the state on Tuesday of each week. By Thursday of each week, the state will have to determine how that allocation is to be distributed within the state so that supplier AmerisourceBergen can put it on trucks and deliver it. If the governor or designee indicates that the state does not want the full amount that has been allocated to it, the rest will remain in the warehouse and either be used for urgent situations that require expedited shipment or will become part of the amount of the following week's therapeutics available for distribution.

## WHAT YOU CAN DO

- Contact your state hospital association to ensure you know who within your state government will be making the allocation decisions and let that person or persons know of your needs.
- Ensure your hospital's data are being submitted to HHS Protect as required, which will ensure your hospital's COVID-19 patients are included in the counts that will determine the amount of monoclonal antibodies allocated to your state.
- Ensure your clinicians understand and are adhering to the criteria for determining who is likely to benefit from this therapy in order to preserve this limited resource for those who truly need it. These criteria are articulated in the [Emergency Use Authorization](#).

## FURTHER QUESTIONS

For further information, please feel free to contact Nancy Foster, AHA's vice president for quality and patient safety, at [nfoster@aha.org](mailto:nfoster@aha.org), or Akin Demehin, AHA's director of policy, at [ademehin@aha.org](mailto:ademehin@aha.org).